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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,237	07/19/2001	Jeffrey B. Miller	08472-720003 / MGH-1176.2	9307
26161	7590	05/05/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			MARVICH, MARIA	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,237

Applicant(s)

MILLER, JEFFREY B.

Examiner

Maria B Marvich, PhD

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-54 is/are pending in the application.
- 4a) Of the above claim(s) 29-31, 37, 38, 40-49, 51, 52 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-28, 32-36, 39, 50 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/19/01.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to a response to a restriction requirement filed 4/19/04. Claims 1-20 have been cancelled. Claims 21-54 are pending in this application.

Election/Restrictions

Applicant's election without traverse of Group II in the amendment filed 4/19/04 is acknowledged. Furthermore, applicants select a cell comprising the stem cell active promoter of claims 27-28. Therefore, claims 29-31, 37-38, 40-49, 51-52 and 54 are withdrawn from consideration as being drawn to nonelected inventions. Claims 21-28, 32-36, 39, 50 and 53 are examined herein.

Information Disclosure Statement

An IDS filed 7/19/01 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. A statement did not accompany the submission of the substitute Paper Copy and Computer

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Readable Form of the Sequence listing, filed 7/23/02, that the substitute sequence listing did not contain New Matter. Applicant must provide a substitute computer readable form (CRF), paper copy of the "Sequence Listing" and a statement that the CRF and "Sequence Listing" are the same and contain no New Matter.

Claim Objections

Claim 39 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Claim 27 already recites that the exogenous nucleic acid sequence is operably linked to a muscle stem cell-active promoter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-28, 32-36, 39, 50 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25, 34-36 and 53 and by dependency claims 26-28, 32-33, 39 and 50 are vague and indefinite in that the metes and bounds of "cells the produce myoblasts" are unclear. While cells can be used to produce proteins, it is unclear how cells can be used to produce other cells.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a genus of promoters that are muscle stem cell-active.

Applicants claim a genus of apoptosis-resistance gene.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

In the instant case, applicants teach that a promoter active in a muscle stem cell can direct transcription in a muscle stem cell. Expression of a reporter gene is considered an indication that the promoter is active in muscle stem cells (see e.g. bridging paragraph page 5-6). Bcl-2 promoters are specifically disclosed as appropriate for this purpose. Neither applicant nor the prior art provide a correlation between the bcl-2 promoter and their muscle stem cell-activity. Given the large size and diverse nature of promoters, and the inability to determine which will also possess muscle stem cell activity, it is concluded that the invention must be empirically

determined. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

In the instant case, applicants do not disclose apoptosis resistance genes. While, applicants describe use of the **cDNA** of Bcl-2 for preparation of probes, applicants do not teach use of the bcl-2 gene or any other apoptosis resistance gene as exogenous genes in muscle stem cells. The genomic version of any recited genes is not disclosed by the specification nor does the prior art apparently disclose the entire gene. While the cDNA may be known, not all of the genes have been characterized. Because all of the components of the gene such as regulation sequences, introns, and exons must be determined empirically in order to generate the apoptosis resistance genes, applicant claims the gene without sufficient disclosure about its structure. The skilled artisan would not conclude that applicant was in possession of viral vector comprising the claimed genes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25-27, 32-36, 50 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (Growth Factors, 1993, 9(1): 57-71; see entire document) in view of Gazit et al (Molecular Endocrinology, February 1993, 7(2):189-198; see entire document).

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Wang et al teach transfection of C3H-10T1/2 cells, a clonal cell line prepared from mouse embryo cells, with BMP-2 cDNA. BMP2 expression is indicative of the promoters operably linked to the coding sequence activity in muscle stem cells. Gazit et al teach that mesenchymal stem cells give rise to myoblasts (see e.g. abstract). Hence mesenchymal stem cell lines such as C3H-10T1/2 are muscle stem cells that lead to myoblast cells.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

April 29, 2004


GERRY LEFFERS
PRIMARY EXAMINER